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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/753,307	09/03/91	[illegible]	

EXAMINER [illegible]/C0221

ART UNIT	PAPER NUMBER
	14

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DATE MAILED: 08/20/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☒ Responsive to communication filed on JULY 7 1992 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☑ Claims 12 & 22 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 12 & 22 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

The Terminal Disclaimer filed 1992 has been found not Acceptable by the Certificates if Correction Branch, Office of Publication, because it is signed y the attorney instead of by the owner of record.

Applicants have submitted two documents, by Britain et al and Bradshaw et al, which have been considered, and are representative of prior art proposing the substitution or replacement of salbutamol by salmeterol, neither describing or suggesting combination therapy with steroids and salmeterol for inhalation therapy of asthma.

Skidmore et al (Glaxo) Great Britain 2,140,800 December 5, 1984 and Jeppson et al, Chem. Abstr. 110:147583r (1989) are at least two prior art instances wherein persons skilled in the art taught prior to applicants' priority date to replace salbutamol with salmeterol for the inhalation therapeutic advantage of longer action instead of short duration. Neither describes salmeterol in combination therapy with a steroid as is conventional for inhalation by asthmatics.

Hunt et al (Glaxo), Great Britain 2,107,715 May 5, 1983 describes pressurized aerosol or dry powder cartridge combination inhalation therapy with the steroid beclomethasone salbutamol (Ex. 6) or another bronchodilator.

Cairns, Great Britain 2,187,953 September 23, 1987 is similar to Hunt et al for such combination therapy.

Radhakrishnan, U.S. 4,906,476 (filed December 4, 1988), (as of that date) establishes art-recognized equivalency for inhalation therapy, not only of steroids such as beclomethasone dipropionate and fluticasone propionate, but also of salmeterol and salbutamol.

Serial No. 578,606, with 7 claims, has been refiled as Serial No. 753,906, with claims 12 to 22. Serial No. 578,601, with 7 claims, has been refiled as 753,907 with claims 12 to 22. In view of the art recognized equivalency of the steroids, as noted above, the common inventor concept of both cases involves no more than the prior art teaching, of Skidmore e al and Jeppson et al, to replace salbutamol with salmeterol, in otherwise conventional asthma inhalation combination therapy with a steroid known to be effective for this purpose.

Claims 12 to 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 to 22 of copending application Serial No. 753,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because art-recognized equivalency of the steroids and of salmeterol to salfutamol, as established in the record by each of Skidmore et al, Jeppson et al and Radhakrishnan (as of December 14, 1988), and the known combination inhalation asthma therapy

shown by Hunt et al and Cairns. This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

SHEP K. ROSE
EXAMINER
ART UNIT 125

ROSE:ebw
August 19, 1992